Pharmacy and Therapeutics Committee

Meeting Minutes

Thursday, September 20, 2018
7:00 a.m. to 8:45 a.m.
Cannon Health Building
Room 125

Committee Members Present:

Clinton Sheffield, MD
McKay Robinson, PharmD
Susan Siegfreid, MD
Elizabeth Young, PharmD
Bryan Larson, PharmD
Clayton Grace, RPh
Cole Sloan, PharmD
Jake Jones, MD

Dept. of Health/Div. of Health Care Financing Staff Present:

Jennifer Strohecker, PharmD, Pharmacy Director
Robyn Seely, PharmD
Joe Busby, RPh, MBA
Merelynn Berrett, RN

University of Utah Drug Regimen Review Center Staff Presenters:

Elena Martinez
Valerie Gonzales, PharmD

Other Individuals Present:

Lori Howarth, Bayer
Jason Russell, Bioverativ
Joanne Yasuda, Pfizer
Dawn Bina, Novo Nordisk
Kevin Kassabian, Shire
Joanita Lake, U of U
Patrick F. Fourtroy, Pfizer
L. R., Pfizer
Joanne LaFluer, U of U
Alex Bitting, Bioverativ
Jeremy Short, Bioverativ
Margaret Fisher, Novo Nordisk
Tamara Pineault, CSL Behring
Rob Meier, Pfizer
Kerri Smith, ViiV
Jason Booth, Lilly
Charissa Anné, J&J
Cody Ball, Select Health

Meeting conducted by: McKay Robinson

1. **Welcome & Housekeeping:** McKay Robinson opened the meeting and announced a quorum.

2. **Review and Approval of July Minutes:** Bryan Larson made a motion to approve the minutes from July. Cole Sloan seconded the motion. Five in favor, Clayton Grace abstained, motion passed. Clinton Sheffield and Jake Jones were not present for this vote.

3. **Drug Utilization Review (DUR) Board update:** The DUR board met last week to discuss Hemlibra, and two prior authorizations. The board did not get to Hemlibra, so that discussion was tabled until the next meeting.

4. **Hemophilia Factor IX:** (Alphanine, Alprolix, Bebulin, Benefix, Feiba, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis). Elena Martinez presented a review of Hemophilia Factor IX products, including the Factor IX based bypassing agent Feiba. She presented peer reviewed research regarding the safety and efficacy of each agent, clinical trials, disease-state treatment guidelines and Utah Medicaid utilization data.

5. **Combination Factor VIII/vWF:** (Alphanate, Humate-P, Wilate, Vonvendi). Valerie Gonzales presented a review of Hemophilia Combination Factor VIII/vWF products. She presented peer reviewed research regarding the safety and efficacy of each agent, clinical trials, disease-state treatment guidelines and Utah Medicaid utilization data.

6. **Public Comment:**
    a. Katheleen Pinto from CSL Behring presented information pertaining to Humate P and Idelvion.
    b. Jeremy Short from Bioverativ presented information pertaining to Alprolix and requested the addition of Alprolix to the Utah Medicaid PDL. Joe Busby asked him for the reference to a study Dr. Short mentioned as showing Alprolix to have better compliance and fewer bleeds than standard therapy. Dr. Short indicated that he will supply the reference.
    c. Kevin Kassabian from Shire presented information pertaining to Rixubis, Feiba, Bebulin, and Vonvendi. Bryan Larson asked if there are plans to seek approval for prophylactic and pediatric indications for Vonvendi. Mr. Kassabian indicated that studies are underway for these uses.
    d. Margaret Fisher from Novo Nordisk presented information pertaining to Rebinyn and requested consideration of Rebinyn for inclusion on the Utah Medicaid PDL. Joe Busby noted that Rebinyn does not have an indication for prophylaxis and asked if that will be sought. Dr. Fisher indicated that Novo Nordisk is actively seeking approval for an indication for prophylaxis.
    e. Bryan Larson read a position statement from the Utah Hemophilia Foundation advocating for patient choice and open availability of all hemophilia treatments.
    f. Bryan Larson read a letter from Octapharma with information pertaining to Wilate.
7. **Other State Report:** Bryan Larson reported PDL listings for agents in this class in other States' Medicaid programs.

8. **Committee Discussion:**
    a. Bryan Larson asked Elena Martinez about the long acting Factor IX products. In the review of Factor VIII products, it was noted that half-lives of Factor VIII products are highly variable and "long acting" is poorly defined. Is this also the case for Factor IX products? Ms. Martinez stated that Factor IX products half-lives are much more consistent across Factor IX products as well as being longer acting than Factor VIII products.
    b. Joe Busby asked if there are any data demonstrating superior outcomes from less frequent dosing. Dr. Gonzales stated that randomized controlled trials have not

demonstrated such differences.

c. Bryan Larson noted that human complex Factor IX products have an increased thrombotic risk relative to other Factor IX products and asked if those products have any unique benefits compared to other Factor IX products. Ms. Martinez indicated that comparative data are unavailable, but guidelines recommend other products over the human complex Factor IX products.
d. Bryan Larson motioned that at least four Factor IX products be preferred on the PDL, with at least two of them being recombinant, and at least one being a long acting recombinant product, and that the Factor IX Complex (Human) are less safe and efficacious and should not be preferred on the PDL. Clinton Sheffield seconded the motion. Unanimous approval, motion passed.
e. Cole Sloan motioned to allow grandfathering with a 90 day lookback. McKay Robinson seconded the motion. Unanimous approval, motion passed.
f. Bryan Larson motioned that at least one bypassing agent be preferred on the PDL. Clinton Sheffield seconded the motion. Unanimous approval, motion passed.
g. Bryan Larson motioned that the treatments for von Willebrand Disease are equally safe and efficacious and that at least two products should be preferred on the PDL with grandfathering with a 90 day lookback. Elizabeth Young seconded the motion. Unanimous approval, motion passed.
h. Cole Sloan asked what the procedure is for handling drug shortages and discontinuations. Bryan Larson responded that a procedure is in place for evaluating requests for non-preferred drugs for which the preferred drug is not available and briefly described that procedure.

9. **Public Meeting Adjourned:** McKay Robinson motioned to close the meeting. Bryan Larson seconded the motion. Unanimous Approval, motion passed.

10. **Next meeting is scheduled for** October 18, 2018 Low Molecular Weight Heparins, Factor Xa Inhibitors**.**

Audio recording of all P&T meetings are available online at:
https://medicaid.utah.gov/pharmacy/pt-committee?p=Committee%20Meeting%20Audio%20Recordings